

# **Exhibit 4**

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EXHIBIT 10(v)

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LICENCE AND SUPPLY AGREEMENT  
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This Agreement made as of 17 January 1996, between ORGANOGENESIS INC., a company organized under the laws of the State of Delaware, of 150 Dan Road, Canton, Massachusetts 02021, USA (hereinafter "Organogenesis") and SANDOZ PHARMA LTD., a corporation organized under the laws of Switzerland, of Lichtstrasse 35, Basle, Switzerland (hereinafter "Sandoz").

W I T N E S S E T H  
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WHEREAS, Organogenesis has certain patents, patent applications and technical information relating to the use and manufacture of GRAFTSKIN skin and tissue equivalents as described in Schedule A (hereinafter "Product"); and

WHEREAS, Sandoz desires to obtain a licence from Organogenesis to use and sell, and under specified conditions, manufacture Product under such patents, patent applications and technical information; and

WHEREAS, Sandoz desires to make an equity investment in Organogenesis;

NOW, THEREFORE, the parties hereto hereby agree as follows:

ARTICLE 1. DEFINITIONS  
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The following terms shall have the following meanings:

1.1 "Affiliate" means any corporation or other entity which controls, is controlled by, or is under common control with, a party to this Agreement. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than forty percent (40%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity.

1.2 "Core Dossier" means the single common core database described in Art. 4.1., which refers to the indications listed in Art. 5.2

1.3 "CPMP" means the European Committee for Proprietary Medicinal Products.

1.4 "Development Phase" means the period from the Effective Date to the date of First Commercial Sale in the last Primary Country to have a First Commercial Sale.

1.5 "Effective Date" means the date first written above.

1.6 "E.U. Countries" means Austria, Belgium, Denmark, Finland, France, Germany, United Kingdom, Greece, Ireland, Italy, Luxembourg; Netherlands, Portugal, Spain, Sweden and such other countries as may in the future join the European Union, in each case for so long as such country remains a member of the European Union.

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1.7 "FDA" means the United States Food and Drug Administration.  
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1.8 "First Commercial Sale" of Product shall mean the first bona fide  
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sale for use or consumption by the general public of Product in a country after required marketing and pricing approval has been granted by the governing health authority of such country.

1.9 "IDE" means a request or approval, as the case may be, in a country  
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in the Territory to initiate human clinical trials of Product in that country; said request or approval intended to correspond to that of an Investigational Device Exemption or an Investigational New Drug in the United States.

1.10 "JDC" means the Joint Development Committee set up according to  
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Art. 4.2.

1.11 "Net Sales" means the gross invoice price of the Product, sold to  
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independent, third-party customers in bona fide, arms-length transactions, less (i) quantity and/or cash discounts actually allowed or taken; (ii) freight postage and insurance (allocated in accordance with Sandoz' standard allocation procedure, which is in accordance with generally acceptable accountancy principles (GAAP)); (iii) amounts repaid or credited by reasons of rejections or return of goods or because of retroactive price reductions specifically identifiable to Product; (iv) amounts payable resulting from Governmental (or agency thereof) mandated rebate programs; (v) third-party rebates to the extent actually allowed; (vi) custom duties and taxes (excluding income, value-added and similar taxes), if any, directly related to the sale; and (vii) any other specifically identifiable amounts included in Product's gross sales that will be credited for reasons substantially equivalent to those listed hereinabove.

1.12 "Patent Rights" means the patents and patent applications relating  
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to Product set out in Schedule B, any divisions, continuations, continuations-in-part, reissues, reexaminations, extensions, supplemental protection certificates or other governmental actions which extend the subject matter or the term of the patent applications or patents above, and any confirmations, registrations or revalidations of any of the foregoing in any additional countries.

1.13 "PMA" means an application for registration and/or approval to  
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manufacture and sell Product in a country in the Territory.

1.14 "PMA Approval" means approval by the health authorities to  
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manufacture and sell Product in a country in the Territory; such approval intended to correspond to a Pre-Marketing Approval of a device or a New Drug Approval by the FDA. In the EU countries, the approval process includes the setting of a reimbursement price.

1.15 "Primary Country" means the United States, Germany, France, Italy  
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and Japan.

1.16 "Supply Price" means the price charged to Sandoz for a three (3)  
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inch diameter circular unit of Product intended for commercial sale.

1.17 "Technical Information" means any or all results and technical  
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information, including preclinical, manufacturing, clinical or regulatory information relating to Product that is (i) owned or controlled by Organogenesis on the Effective Date; or (ii) hereinafter developed or acquired by Sandoz or Organogenesis during the term hereof.

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1.18 "Territory" means all countries in the world.  
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1.19 "Valid Patent Claim" means either (a) a claim of an issued and  
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unexpired patent included within the Patent Rights, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a claim of a pending patent application included within the Patent Rights, which claim was filed in good faith and has not been abandoned or finally disallowed.

1.20 "\*\*\*\*\*" means Sandoz's \*\*\*\*\* based on the \*\*\*\*\* \*\*\*\*\* , \*\*\*\*\* \*\*\*\*\* , \*\*\*\*\*and \*\*\*\*\* of Product in the \*\*\*\*\* as calculated in accordance with \*\*\*\*\*.

## ARTICLE 2. LICENCE GRANT -----

2.1 Scope of Grant: Organogenesis hereby grants to Sandoz an exclusive  
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licence, or, where applicable, an exclusive sublicense, under Patent Rights and Technical Information to use, import, sell and offer to sell Product in the Territory and, under the circumstances set forth in Art. 12, to make and have made Product in the Territory. The licence so granted includes the right to sublicense. Sandoz shall provide written notice to Organogenesis concerning each sublicense granted hereunder, other than those to Affiliates, together with a copy of each sublicense agreement, within fifteen (15) days after execution thereof. During the Development Phase, Sandoz will review through the JDC its licensing strategy relating to Product, including the names of potential sublicensees. Organogenesis shall have the right to request that Sandoz sublicense Product in any country in which Sandoz has no plans to commercialize Product, and Sandoz shall consider any such request in good faith.

2.2 Exclusivity Term in E.U.: Respecting E.U. Countries, the  
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exclusivity provided by Organogenesis shall be limited to a period of ten (10) years from the Effective Date, provided, however, that in the E.U. Countries in which Patents remain valid after expiration of the ten-year period, the exclusivity will continue until expiration of Patents. For avoidance of doubt, Sandoz acknowledges that termination of exclusivity in E.U. Countries pursuant to the preceding sentence shall not reduce, impair or otherwise affect Sandoz' obligation to continue to pay royalties provided in Article 6, hereof, in such countries.

2.3 MIT Licence: Organogenesis is the exclusive licensee of  
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Massachusetts Institute of Technology (MIT) to US Patent 4,485,096, and equivalents which are included in the Patent Rights set out in Schedule B of this Agreement. Organogenesis' licence will end when patent USP 4,485,096 expires.

## ARTICLE 3. TECHNICAL INFORMATION -----

Organogenesis shall disclose to Sandoz the Technical Information within thirty (30) days of the Effective Date. Organogenesis and Sandoz shall further disclose to one another all Technical Information hereinafter developed or acquired by either party during the term of this Agreement. The parties shall also disclose to one another reimbursement studies, market research

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and manufacture and distribution plans developed or acquired by either party prior to the Effective Date or during the term of this Agreement. Organogenesis warrants that preclinical testing, including safety testing, within the Technical Information has been carried out according to Good Laboratory Practice, and that clinical testing within the Technical Information has been carried out according to Good Clinical Practice.

#### ARTICLE 4. DEVELOPMENT OF PRODUCT

4.1 Responsibilities: Organogenesis will execute the development and registration activities in the U.S.; Sandoz will plan and execute the development and registration activities outside the U.S. Nevertheless, all information, data and study results shall be shared between the parties, and the parties shall develop a single common core database in respect of all clinical studies (the "Core Dossier"). The studies in the Core Dossier shall be performed to CPMP and FDA standards. Organogenesis shall own the PMA and all other regulatory approvals relating to Product in the U.S.; and Sandoz shall own the PMA and all other regulatory approvals relating to Product outside the U.S.. Each party shall upon request provide the other with copies of the regulatory approval documents certified by an appropriate officer of such party.

4.2 Joint Development Committee: Sandoz and Organogenesis will, within fifteen (15) days after the Effective Date, establish a Joint Development Committee ("JDC") to oversee the global development activities, having the objective of achieving global registration of Product in the most expeditious fashion. The JDC shall agree on the strategy for performing the studies to be included in the Core Dossier.

4.3 Membership: The JDC shall be comprised of three (3) representatives from each of Sandoz and Organogenesis. Each party may replace its JDC representatives at any time, after discussion with the other party, with subsequent written notice to the other party. Organogenesis and Sandoz shall each appoint one of their JDC representatives to be responsible for coordinating communications between Organogenesis and Sandoz (the "Primary Contact Person"). The JDC shall be chaired by the Sandoz Primary Contact Person.

4.4 Decision Making: Decisions of the JDC shall be made by majority approval. In the event the parties are unable to agree on an issue concerning the Core Dossier that has no financial impact on Organogenesis, Sandoz shall make the final decision. In the event the parties are unable to agree on any other issue, the dispute will be referred to Organogenesis's President (or designee of similar rank) and Sandoz's Head of Business Development (or designee of similar rank), who shall promptly meet in person or by means of telephone or video conference and endeavor to resolve the dispute in a timely manner. In the event such individuals are unable to resolve the dispute, it shall be settled by binding arbitration pursuant to Art. 18.11 below, or as otherwise agreed.

4.5 JDC Meetings: During the Development Phase, the JDC shall meet at least quarterly at regular intervals, or more often as agreed by the parties, in person at such locations as the parties agree, or by means of telephone or video conference. With the consent of the parties, other representatives of Organogenesis or Sandoz or its Affiliates or Sublicensees may attend JDC meetings as nonvoting observers. The party hosting a particular JDC meeting shall promptly prepare and deliver to the members of the JDC, within thirty (30) days after the date of each meeting, minutes of such meeting setting forth, inter alia, all decisions of the JDC. In case of telephone and video conferences, this responsibility will alternate between the parties.

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4.6 Funding: Sandoz shall make the following payments to Organogenesis  
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as a contribution to Organogenesis' research and development costs, including clinical trial and registration costs, in the U.S.:

Due Date	Amount
*****	***** *****
*****	***** *****
*****	***** *****

The initial equity investment of \*\*\*\*\* referred to in Art. 8.1 shall also be applied to Organogenesis' research and development costs including clinical trial and registration costs in the U.S. associated with studies agreed upon by the JDC and described in the Core Dossier, making a total contribution from Sandoz of \*\*\*\*\*.

(i) All additional research and development, and registration costs required for the Core Dossier in the U.S. will be borne by Organogenesis.

(ii) All additional clinical trial costs related to the Core Dossier in the U.S. determined by the FDA to be necessary or appropriate shall be borne by Organogenesis.

(iii) All additional clinical trial costs unrelated to the Core Dossier in the U.S. determined by the JDC to be necessary or appropriate shall be borne by Sandoz (including, for example, post market surveillance studies and trials for additional indications not listed in Art. 5.2).

(iv) Research and development unrelated to the Core Dossier but directed towards registration in additional indications and determined by the JDC to be appropriate for action will be funded by Sandoz.

An annual budget for U.S. research and development and clinical activities will be prepared by Organogenesis and approved by the JDC at least ninety (90) days before the end of each calendar year. All clinical trial and registration costs incurred outside the U.S. will be borne by Sandoz. An annual plan and budget for European development activities will be prepared by Sandoz and submitted to the JDC at least ninety (90) days before the end of each calendar year.

4.7 Cooperation: Upon request of Sandoz, Organogenesis shall file with  
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the health authorities in the Territory and permit Sandoz to cross-refer to such file, or provide to Sandoz and allow Sandoz to file with the authorities, information concerning the manufacturing process and quality control of Product required under local laws to support the registration of Product, including any necessary validation of additional master cell banks. Subject to the above provisions, Sandoz and its Affiliates shall commence marketing of Product in each Primary Country promptly upon receiving necessary PMA Approval (including approval for pricing, where applicable) and shall promptly notify Organogenesis, through the JDC, of commencement of such marketing. Each party agrees to disclose to the other party data from clinical studies, as well as data from marketing and medical support activities relevant to future product development activities.



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#### 4.8 Reasonable Commercial Efforts and Excused Performance:

##### 4.8.1 Reasonable Commercial Efforts: Sandoz agrees to use reasonable

commercial efforts to obtain PMA approval in each Primary Country other than the US and to market and sell Product in all Primary Countries as promptly as is reasonably practicable. Organogenesis agrees to use reasonable commercial efforts to obtain PMA approval in the U.S. as promptly as is reasonably practicable.

##### 4.8.2 Excused Performance: Sandoz's obligations with respect to Product

under Art. 4.8.1 are expressly conditioned upon the continuing absence of any adverse conditions relating to the safety, quality or efficacy of Product, price or other restrictions imposed by governmental authorities under which the sale of Product would not produce a reasonable profit, the reasonable likelihood of the infringement of a patent or other proprietary rights of third parties or other condition or event beyond Sandoz's control that would reasonably justify Sandoz, after consulting with Organogenesis, in exercising prudent and justifiable business judgement, concluding that development or marketing of Product should be delayed, suspended or stopped altogether, and Sandoz's obligation to develop or market Product shall be delayed or suspended so long as any such condition or event exists.

##### 4.9 Improvements: Organogenesis agrees to disclose and furnish to

Sandoz, without charge, information on any inventions and/or improvements for Product obtained by Organogenesis during the term of this Agreement, regardless of whether such inventions and/or improvements are patentable. Sandoz shall have the right and option, at its sole election, to obtain an exclusive licence to any such invention by providing written notice to Organogenesis of such election within ninety (90) days after Organogenesis notifies Sandoz in writing that it has filed a patent application for such invention. Upon any such election, such invention shall be deemed to be part of the Patent Rights, and the licence provisions of Art. 2 and the royalty provisions of Articles 6 and 7 together with all other applicable provisions, shall apply to such invention.

#### ARTICLE 5. MILESTONE PAYMENTS

##### 5.1 Europe: Upon receiving the first PMA Approval to be granted for one

of the European Primary Countries, that is, for Germany, Italy or France, Sandoz shall make to Organogenesis a single non-refundable payment of \$\*\*\*\*\*  
\*\*\*\*\*. Subsequent PMA approvals in the same country or in the other European Primary Countries shall not trigger additional milestone payments.

##### 5.2 U.S.: Upon supply by Organogenesis to Sandoz of sufficient Product

to support Sandoz' introduction of Product following PMA Approval in the U.S. for each of the listed indications, Sandoz shall pay Organogenesis non-refundable milestone payments in accordance with the following schedule:

Indication	Amount
Venous stasis ulcers	*****
Dermatologic surgery	*****
Diabetic ulcers	*****
Burn therapy	*****
Decubitus ulcers	*****



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#### ARTICLE 6. ROYALTIES

##### 6.1 Royalty levels and term: As further consideration for the licence

granted and Technical Information provided hereunder, Sandoz shall pay Organogenesis the following royalties as a percentage of Net Sales of Product made by Sandoz, its Affiliates and sublicensees:

- (i) in a country in which sale of Product would, but for the licence granted hereunder, infringe a Valid Patent Claim, a patent royalty of \*\*\*\*\* payable until the expiration of the last of the Patent Rights which would be so infringed in that country.
- (ii) in a country where sale of Product would not infringe a Valid Patent Claim, a know-how royalty of \*\*\*\*\* payable until \*\*\*\*\* from the First Commercial Sale in that country.
- (iii) in a country [covered by Art. 6.1(i) above] in which the term of the patent royalty is less than \*\*\*\*\* from the Effective Date, a know-how royalty of \*\*\*\*\* for the period beginning at expiration of patent royalties and ending \*\*\*\*\* from the First Commercial Sale in that country.

For the purposes of this Art. 6.1, Net Sales by Sandoz to an Affiliate or sublicensee shall not be counted for royalty purposes (unless the Affiliate or sublicensee is the end user of the Product); instead, the Net Sales of such Affiliate or sublicensee to an unrelated third party shall be considered Net Sales for royalty purposes.

##### 6.2 Increased Royalties on Incremental Sales: Subject to adjustment

according to Art. 6.4, if, in any calendar year, in any of the three following areas: (a) the U.S., (b) Japan, and (c) the E.U. Countries taken together, the Net Sales of Product which would, but for the licence granted hereunder, infringe a Valid Patent Claim should exceed \*\*\*\*\* then the patent royalty payable on such Net Sales shall be \*\*\*\*\* on the first \*\*\*\*\* of Net Sales in such calendar year, and \*\*\*\*\* on all incremental Net Sales above this amount.

##### 6.3 Third Party Royalties: If Sandoz is required to pay royalties to

any third party in order to exercise its rights to sell Product, then \*\*\*\*\* of the royalties payable to such third party shall be deductible from the royalties paid to Organogenesis under this Agreement, provided that

- (i) in no event shall any royalty payment under Art. 7.2 be reduced by more than \*\*\*\*\* with the non-deducted amounts carried forward for future deduction, and
- (ii) in no case shall the patent royalty rate be less than \*\*\*\*\* in countries in which sale of Product would, but for the licence granted hereunder, infringe a Valid Patent Claim,
- (iii) nor shall the know-how royalty rate be less than \*\*\*\*\*.

##### 6.4 Royalty Adjustment: If in any country in which sale of Product

falls under a Valid Patent Claim, a third party markets a competing skin equivalent product which prima facie infringes a Valid Patent Claim, then if the competing product achieves in any calendar year unit

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sales of at least \*\*\*\*\* of Sandoz' unit sales of Product in such country, the royalty rates payable by Sandoz on Net Sales of Product in the following calendar year according to Articles 6.1 and 6.2 shall be reduced by \*\*\*\*\* provided that if the country is other than the United States, such royalty reduction shall apply only if Sandoz has taken appropriate legal action to abate the infringement and is diligently pursuing such action. If as a result of such legal action the competing product is removed from the market, the reduction in royalty rate shall cease to apply with immediate effect.

6.5 \*\*\*\*\*: For each country, \*\*\*\*\* Sandoz shall have a \*\*\*\*\* under any remaining know-how or other rights of Organogenesis, to use and sell Product in that country. After expiration of this Agreement according to Art. 16.1, and subject to any Supply Agreement as contemplated in Art. 12.1, Sandoz shall have a \*\*\*\*\* under any remaining know-how or other rights of Organogenesis, to make or have made Product.

#### ARTICLE 7. RECORDS AND PAYMENTS

7.1 Development Funding and Milestone Payments: Payments to be made under Articles 4.6 and 5.2 shall be paid by Sandoz upon presentation of an invoice by Organogenesis. Payment shall be made no later than (a) the due date or (b) thirty (30) days after receipt of the corresponding invoice, whichever is the later.

7.2 Royalties: Royalties as provided in Article 6 shall be calculated \*\*\*\*\* on the last day of each calendar \*\*\*\*\* during the term of this Agreement and shall be paid to Organogenesis within \*\*\*\*\* (\*\*) \*\*\*\* after said last day with an accounting report showing the amount of Product sold by Sandoz and its Affiliates and sublicensees during each \*\*\*\*\* period.

7.3 Currency Exchange: Royalties provided to Organogenesis shall be made in US Dollars, and shall be determined on the basis of Sandoz' monthly standard account of sales which represents the conversion of all local currency sales to Swiss Francs at the average monthly exchange rate of sales. The average exchange rate between the Swiss Franc and US Dollar shall be the rate published in the London Times at the close of business in London on the \*\*\*\*\* \*\*\*\*  
\*\*\*\*\* for which the royalties are being paid.

7.4 Method of Payment: Royalties and payments provided to Organogenesis shall be made by telegraphic transfer to Organogenesis's bank account at the following address:

State Street Bank & Trust Company  
225 Franklin Street  
Boston, MA 02110

ABA: 011-0000-28 Account 5182-768-1

7.5 Records: Sandoz shall keep accurate records and books of accounts in accordance with generally accepted accounting principles consistently applied and containing all the data reasonably required for calculation and verification of payments made. During the term of this

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Agreement and two (2) years thereafter, Sandoz shall retain accounting records of the previous three (3) years. At Organogenesis's request, Sandoz shall make records available, no more than twice per year, during reasonable working hours for review by an independent accounting firm acceptable to both parties, at Organogenesis's expense, for the sole purpose of verifying their accuracy. In the event that any such review indicates an underpayment of royalties by Sandoz in excess of five percent (5%), Sandoz shall pay the cost of such review.

7.6 Taxes: All royalty amounts required to be paid to Organogenesis

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pursuant to this Agreement shall be paid with deduction for withholding for or on account of any taxes (other than taxes imposed on or measured by net income) or similar governmental charge imposed by a jurisdiction other than the U.S. ("Withholding Taxes"). Sandoz shall provide Organogenesis a certificate evidencing payment of any Withholding Taxes hereunder and provide reasonable assistance to recover such taxes.

ARTICLE 8. EQUITY INVESTMENT

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Sandoz shall make one or more equity investments in Organogenesis according to the terms and conditions set out in the Stock Purchase Agreement between them of even date herewith.

ARTICLE 9. PATENT PROSECUTION AND MAINTENANCE

9.1 Responsibility: Within ninety (90) days of the Effective Date,

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Sandoz shall assume cost and responsibility for prosecution and maintenance of the Patent Rights outside the U.S. Organogenesis shall continue to bear cost and responsibility for prosecution and maintenance of the Patent Rights in the U.S. Each party shall provide the other with copies of substantive communications to and from the applicable patent offices.

9.2 Discontinuation: Sandoz may elect upon sixty (60) days prior notice

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to discontinue prosecution or maintenance of any of the Patent Rights in any or all countries for which Sandoz is responsible. In such case, Organogenesis shall have the right to prosecute and maintain such patent applications and patents in such countries it deems appropriate, at its sole expense. Any such patent application or patent in such country which Organogenesis prosecutes or maintains shall no longer be part of the Patent Rights and shall be excluded from the licence granted to Sandoz under this Agreement.

9.3 Foreign Filing Decisions: If after the end of the ninety (90) day

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period referred to in Art. 9.1 there exists any U.S. patent application which is part of the Patent Rights as of the Effective Date or which becomes part of the Patent Rights by the provisions of Art. 4.9 and for which no corresponding foreign applications have yet been filed, the parties shall consult at an appropriate time as to whether, and if so in which countries, such foreign filing should be carried out by Sandoz and at Sandoz' expense. If in any one of the following countries: Australia, Canada, Israel, Japan, Korea, Mexico, Taiwan and the countries of the European Patent Convention, Sandoz decides not to file a corresponding application, Organogenesis shall have the right to file a corresponding application in such country, at its sole expense. Any such patent application or patent granted thereon in such country which Organogenesis prosecutes or maintains shall no longer be part of the Patent Rights and shall be excluded from the licence granted to Sandoz under this Agreement.

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#### ARTICLE 10. PATENT INFRINGEMENT

10.1 Warranty: Organogenesis represents and warrants that, to its knowledge, there exists no publication or other reason that would adversely affect the patentability of the subject-matter of or the validity of the Patent Rights and that it has no information as of the Effective Date to indicate that Sandoz would not be free to make, use and sell Product in the Territory without infringing any third party patent.

10.2 Enforcement: Each party shall promptly notify the other of its knowledge of any potential infringement of the Patent Rights by a third party. Organogenesis has the right, but not the obligation, to take reasonable legal action necessary to enforce the Patent Rights in the United States against infringements by third parties. If within six (6) months following receipt of such notice from Sandoz, Organogenesis fails to take such action to halt a commercially significant infringement, Sandoz shall, in its sole discretion, have the right, at its expense, to take such action in its own name or in the name of Organogenesis or jointly. Sandoz shall have the right to enforce the Patent Rights in countries other than the United States in its discretion. If within six (6) months following receipt of notice from Organogenesis, Sandoz fails to take such action to halt a commercially significant infringement, Organogenesis shall, in its sole discretion, have the right, at its expense, to take such action in its own name or in the name of Sandoz or jointly. Each party agrees to render such reasonable assistance as the prosecuting party may request. Costs of maintaining any such action and damages recovered therefrom shall be paid by and belong to the party bringing the action. Sandoz shall not enter into any settlement which admits or concedes that any aspect of the Patent Rights is invalid or unenforceable without the prior written consent of Organogenesis.

10.3 Infringement Claims: If the manufacture, sale or use of Product pursuant to this Agreement results in any claim, suit or proceeding lodged by a third party alleging patent infringement by Organogenesis or Sandoz (or its Affiliates or Sublicensees), such party shall promptly notify the other party hereto in writing. The party subject to such claim shall have the exclusive right to defend and control the defense of any such claim, suit or proceeding, at its own expense, using counsel of its own choice; provided, however, that Sandoz shall not enter into any settlement which admits or concedes that any aspect of the Patent Rights is invalid or unenforceable without the prior written consent of Organogenesis. The party subject to the claim shall keep the other party hereto reasonably informed of all material developments in connection with any such claim, suit or proceeding.

#### ARTICLE 11. TRADEMARKS

Sandoz and its Affiliates shall be free to use and to register in any trademark office any trademark for use with Product they desire in their sole discretion. Sandoz shall own all right, title and interest in and to any trademark in its own name or that of its Affiliates during and after the term of this Agreement. At Sandoz' request, Organogenesis agrees to exclusively license to Sandoz free of charge all rights in the trademark GRAFTSKIN.

#### ARTICLE 12. MANUFACTURING AND SUPPLY

12.1 Supply by Organogenesis: Subject to Art. 12.3 below, Sandoz agrees to purchase exclusively from Organogenesis, and Organogenesis agrees to sell exclusively to Sandoz during

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the term of the Agreement, Sandoz' total worldwide requirements for Product. No later than three (3) months after the Effective Date, the parties shall enter into a separate Manufacturing and Supply Agreement which shall provide, among other matters, for the setting up of a Joint Manufacturing Committee to ensure adequate supplies of Product including setting strategies for the European Manufacturing Facility described in Art. 12.3 below; for a system of advance ordering of requirements by Sandoz; and for quality control of Product. Such Manufacturing and Supply Agreement shall terminate no later than the expiry of the present Agreement in all countries under Art. 16.1. No later than six (6) months before such date, Sandoz shall notify Organogenesis whether it wishes to extend the supply period for all or part of Sandoz's worldwide requirements for Product for a further period, in which case a further Supply Agreement will be negotiated in good faith and entered into by the parties. If no such further Supply Agreement is concluded between the parties, then Sandoz shall have the right to manufacture Product itself or have Product manufactured by a third party of its choice, based on full technical assistance and know-how, including full documentation, relating to Product and Improvements to be supplied free of charge by Organogenesis.

#### 12.2 U.S. Manufacturing Facility: Organogenesis will assume full cost

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and responsibility for constructing, operating and maintaining a U.S. manufacturing facility capable, in conjunction with any European manufacturing facility as provided for in Art. 12.3 below, of supplying the expected commercial requirements of Sandoz worldwide in accordance with the supply provisions of Art. 12.1 above, and with the provisions of the Manufacturing and Supply Agreement to be entered into by the parties. Such Manufacturing and Supply Agreement shall provide that if Organogenesis is unable to supply more than a certain percentage, to be negotiated, of Sandoz' duly forecasted requirements of Product meeting the agreed specifications, then Sandoz shall thereafter have the right to manufacture Product itself or to have Product manufactured by a third party of its choice, based on full technical assistance and know-how, including full documentation, relating to Product and Improvements to be supplied free of charge by Organogenesis. In the event that such inability to supply is proved to be due to negligence on the part of Organogenesis, then no royalties shall be payable on Net Sales of Product during a time sufficient for Sandoz to recover out of the royalties that would otherwise be paid to Organogenesis such lost profits as it may have sustained as a result of Organogenesis' inability to supply; thereafter royalties shall be payable as before.

#### 12.3 European Distribution Center and Manufacturing Facility: Sandoz

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agrees to invest up to \*\*\*\*\* in the construction of a new facility at one of Sandoz' existing manufacturing sites in Europe, said facility to consist of a) a Distribution Centre for the thawing of cryopreserved Product and distribution of Product to end users in Europe, and b) "shell" premises (building and basic utilities) capable of being equipped as a manufacturing facility for Product. Upon Sandoz' receipt of building permission for such facility or by \*\*\*\*\*, whichever is later, Organogenesis shall have the option of leasing and operating such facility under the terms of a separate Leasing Agreement to be entered into between the parties, which Agreement shall provide, among other matters, for repayment of Sandoz's investment plus reasonable interest over a period of not more than ten (10) years. If Organogenesis exercises such option, Organogenesis shall fund all additional costs of said facility, including equipment and operating costs. If Organogenesis does not exercise such option, or if Organogenesis, having exercised such option, does not within one (1) month of the date on which the option was exercised begin site planning and place orders for the purchase of all necessary equipment, then Sandoz shall have the right within Europe to manufacture Product itself or have Product



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manufactured by a third party of its choice, based on full technical assistance and know-how, including full documentation, relating to Product and Improvements to be supplied free of charge by Organogenesis.

12.4 Supply Price: For a period of eighteen (18) months from the First

Commercial Sale of Product in the first Primary Country in the Territory, the Supply Price shall be \*\*\*\*\*. Within three (3) months from the end of said period the Supply Price shall be reviewed by the parties in good faith, and shall \*\*\*\*\* unless the \*\*\*\*\* on sales of Product is \*\*\*\*\* in which case the Supply Price shall be \*\*\*\*\* so as to \*\*\*\*\*.

Thereafter, if in any June or December in a calendar year within the term of this Agreement, Sandoz can demonstrate to Organogenesis that its \*\*\*\*\* sales of Product in the last six (6) month period for which Sandoz has sales records was \*\*\*\*\* then Organogenesis agrees \*\*\*\*\* the Supply Price and/or the royalty level, effective from the beginning of the following half year, so as to assure Sandoz that \*\*\*\*\* in the following half year. Any figures relied upon by Sandoz to support its \*\*\*\*\* shall be open to review by an independent accounting firm acceptable to both parties, at Organogenesis's expense, for the sole purpose of verifying their accuracy. The price charged to Sandoz for a four by eight (4 x 8) inch rectangular unit of Product shall be negotiated in good faith by the parties at such time as Sandoz is able to provide sales volume projections for units of this size. The \*\*\*\*\* Supply Price of \*\*\*\*\* per unit shall be subject to annual adjustment to reflect changes in Sandoz' average selling price in the Primary Countries, starting two (2) years after the First Commercial Sale of Product in the first Primary Country in the Territory.

12.5 Non-Commercial Supply: All quantities of Product reasonably

required by Sandoz for commercial samples and clinical trials shall be supplied by Organogenesis at a price of \*\*\*\*\* per unit in the first year following the Effective Date, \*\*\*\*\* per unit in the second year, and \*\*\*\*\* per unit thereafter, subject to annual adjustment to reflect changes in the U.S. Consumer Price Index, starting from 1 January 2000.

ARTICLE 13. DISTRIBUTION

Sandoz will assume cost and responsibility for shipping Product from the manufacturing facility in the United States to the end user in the United States. Organogenesis will assume cost and responsibility for shipping Product in bulk to a designated distribution center in Europe for sale of Product in Europe and for the packaging of Product within said distribution center (including any necessary thawing step), and Sandoz will assume cost and responsibility for delivering Product from said distribution center to the end user in Europe.

ARTICLE 14. PRODUCT LIABILITY

14.1 Negligence: Organogenesis shall indemnify and hold Sandoz harmless

from all losses, costs or damages which Sandoz may be held liable to pay as a result of claims or suits arising out of any injuries to persons and/or damage to property arising from Organogenesis's negligence with respect to the subject matter of this Agreement. Sandoz shall indemnify and hold Organogenesis harmless from all losses, costs or damages which Organogenesis may be held liable to pay as a result of claims or suits arising out of any injuries to persons and/or damage to

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property arising from Sandoz' negligence with respect to the subject matter of this Agreement.

14.2 Other Claims: Third party claims not related to negligence of

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either party shall be handled as agreed by the insurance companies of the parties (both parties agree to have sufficient third party liability insurance and/or self coverage) or in accordance with the laws of the country or countries in which a claim is submitted.

14.3 Tissue Donor Release: Organogenesis warrants that any donor of

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tissue used to generate the cell bank used in the manufacture of Product, or his parent or guardian, has signed or shall sign a release giving informed consent to the use of the tissue for commercial purposes.

14.4 Reporting: Each party hereto agrees to report promptly to the

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other party any information concerning serious or unexpected side effects, injury, toxicity, reactions or any unexpected event associated with clinical, investigational or commercial use whether or not finally attributable to Product. Such information shall also include pre-existing diseases, syndromes, or abnormal diagnostic tests results which re-appear or are exacerbated by use of Product. Upon receipt of such information by either party hereto, both parties shall promptly consult each other and use best efforts to arrive at a mutually acceptable procedure for taking the appropriate actions under the circumstances; provided, however, that nothing contained herein shall restrict the right of either party to make a submission to a regulatory authority or take other actions it deems to be appropriate or necessary. This Article shall survive termination of this Agreement.

ARTICLE 15. SECRECY

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15.1 Confidential Information: Except as contemplated by this

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Agreement, any information supplied by one party to the other pursuant to, or in contemplation of, this Agreement shall be retained in confidence and not used or disclosed by the recipient during the term of this Agreement and for five (5) years thereafter. The confidentiality obligations provided herein shall not apply to information which

- (i) is or becomes known publicly through no fault of the receiving party;
- (ii) is obtained by the receiving party without duty of non-disclosure from a third party entitled to disclose it;
- (iii) was already known by the receiving party at the time of disclosure hereunder as shown by prior written records of the receiving party; or
- (iv) is developed by the receiving party independently of information obtained or disclosed hereunder.

15.2 Permitted use: Notwithstanding the provisions of the above, each

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party shall have a right to use such information for development, production and marketing of Product as provided in this Agreement and further has a right to disclose such information to a governmental agency or other competent body as and when required by law and regulation.

15.3 Nondisclosure of terms: Each of the parties agrees not to disclose

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to any third



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party the terms of this Agreement without the prior written consent of the other party, except to such party's attorneys, advisors, investors and others on a need to know basis under circumstances that reasonably ensure the confidentiality thereof, or to the extent required by law (including, but not limited to, disclosure required by U.S. securities laws). Notwithstanding the foregoing, the parties shall agree upon a press release to announce the execution of this Agreement, thereafter, Organogenesis and Sandoz may each disclose to third parties the information contained in such press release without the need for further approval by the other. Other than the above, Organogenesis, its officers and employees shall not make any public statements relating to Product or to this Agreement without the prior written consent of Sandoz.

#### ARTICLE 16. TERM AND TERMINATION

16.1 Term: Except as set forth below, the term of this Agreement shall begin as of the Effective Date and continue in full force and effect, on a country-by-country basis, unless terminated earlier as provided in this Article 16, until Sandoz, its Affiliates and Sublicensees have no remaining royalty payment obligations in any country.

16.2 Termination for Cause: Either party to this Agreement may terminate this Agreement in the event that the other party shall have materially breached or defaulted in the performance of any of its material obligations hereunder, and such default shall have continued for sixty (60) days after written notice thereof was provided to the breaching party by the non-breaching party. Any termination shall become effective at the end of such sixty (60) day period unless the breaching party has cured any such breach or default prior to the expiration of the sixty (60) day period.

16.3 Termination for Insolvency: If voluntary or involuntary proceedings by or against a party are instituted in bankruptcy under any insolvency law, or a receiver or custodian is appointed for such party, or proceedings are instituted by or against such party for corporate reorganization or the dissolution of such party, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing, or if such party makes an assignment for the benefit of creditors, or substantially all of the assets of such party are seized or attached and not released within sixty (60) days thereafter, the other party may immediately terminate this Agreement effective upon notice of such termination.

16.4 Permissive Termination: At any time after eighteen (18) months after the Effective Date, Sandoz may terminate this Agreement upon ninety (90) days written notice in the event it discontinues development of Product for reasons in Sandoz' reasonable judgement related to safety or efficacy of the Product, or in the event it judges unforeseen competitive developments as having a substantial and irreversible negative impact on Product's chances for commercial success, or if even after agreed adjustments to royalties and supply price as provided in Articles 6.4.2 and 12.4, it proves impossible for Sandoz to achieve \*\*\*\*\* in at least \*\*\*\*\* of the Primary Countries.

16.5 Termination Due to Acquisition: If any Third Party which is a competitor of Sandoz shall purchase substantially all the assets of Organogenesis or if there is a change of control of Organogenesis, Sandoz may terminate this Agreement upon ninety (90) days written notice. As used herein, change of control shall mean the acquisition by a third party which is a competitor of Sandoz of forty percent (40%) or more of the voting stock of Organogenesis.

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16.6 Effect of Termination:  
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16.6.1 Upon termination of this Agreement by Organogenesis in accordance with Article 16.2 or 16.3, or by Sandoz in accordance with 16.4 or 16.5, the licences granted to Sandoz hereunder shall be forthwith terminated, and Sandoz shall cease to develop and market Product and discontinue the use of, and return to Organogenesis within sixty (60) days after termination, all Technical Information (including IDEs and PMAs, if any) and shall assign, free of charge, to Organogenesis, any governmental approvals to assure an orderly transfer of rights and transition of responsibility for such documentation. Notwithstanding the above, Sandoz may sell existing inventory of Product for up to six (6) months after the date of termination, provided royalties are paid thereon.

16.6.2 Upon termination of this Agreement by Sandoz in accordance with Article 16.2, or 16.3, Sandoz shall be assigned free of charge the ownership of the PMA and all other regulatory approvals relating to Product in the U.S., and shall be entitled to maintain the licences granted hereunder after said termination under the same conditions as set forth in this Agreement including the right to manufacture Product or have Product manufactured by a third party based on full technical assistance and know-how, including full documentation, relating to Product and Improvements to be supplied free of charge by Organogenesis; provided, however, in the event of a termination pursuant to Art. 16.2, all payments set forth therein to be made by Sandoz following said termination shall be reduced by one-half without prejudice to any damages to which Sandoz may be entitled.

16.6.3 Termination of this Agreement for any reason shall not release any party hereto from any liability which, at the time of such termination, has already accrued to the other party or which is attributable to a period prior to such termination nor preclude either party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

16.7 Survival: Articles 14, 15, 16 & 18 of this Agreement shall survive  
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the expiration or termination of this Agreement for any reason.

ARTICLE 17. NOTICES  
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Any notices required or provided for by the terms of this Agreement shall be in writing and any notices, statements, and payments provided hereunder shall be sent by registered or certified mail, postage prepaid, addressed to:

In case of Organogenesis:	Organogenesis Inc. 150 Dan Road Canton, MA 02021 USA Attention: President
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In case of Sandoz:	Sandoz Pharma Ltd. Lichtstrasse 35 CH-4002 Basle, Switzerland Attention: Legal Department
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Such notices, statements and payments shall be deemed to have been given or made on the date upon which said letter was registered or certified, but any presumption of actual notice or payment shall be subject to rebuttal by the party alleged to have received such notice or payment to show that such notice or payment has not actually been received.

ARTICLE 18. MISCELLANEOUS; PROVISIONS  
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18.1 Governing Laws: This Agreement and any dispute arising from the construction, performance or breach hereof shall be governed by and construed and enforced in accordance with, the laws of the state of New Jersey.

18.2 No Implied Licences: Only the licences granted pursuant to the express terms of this Agreement shall be of any legal force or effect. No licence rights shall be created by implication, estoppel or otherwise.

18.3 Waiver: It is agreed that no waiver by any party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default.

18.4 Assignment: This Agreement shall not be assignable by either party to any third party hereto without the written consent of the other party hereto except in the case of Sandoz to its designated Affiliate(s), except that, subject to Section 16.5, either party may assign this Agreement, without such consent, to an entity that acquires all or substantially all of the business or assets of such party, whether by merger, reorganization, acquisition, sale, or otherwise. This Agreement shall be binding upon and inure to the benefit of any permitted assignee, and any such assignee shall agree to perform the obligations of the assignor. Sandoz may, without assignment of the entire Agreement, assign any of its rights and obligations under this Agreement to a designated Sandoz Affiliate.

18.5 Independent Contractors: The relationship of the parties hereto is that of independent contractors. The parties hereto are not deemed to be agents, partners or joint venturers of the others for any purpose as a result of this Agreement or the transactions contemplated thereby.

18.6 Compliance with Laws: In exercising their rights under this licence, the parties shall fully comply in all material respects with the requirements of any and all applicable laws, regulations, rules and orders of any governmental body having jurisdiction over the exercise of rights under this licence including, without limitation, those applicable to the discovery, development, manufacture, distribution, import and export and sale of medical products pursuant to this Agreement.

18.7 Severability: In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision, and the parties shall amend the Agreement to the extent feasible to lawfully include the substance of the excluded term to as fully as possible realize the intent of the parties and their commercial bargain, unless the invalid provision is of such essential importance to this Agreement that it is to be reasonably assumed that the parties would not have entered into this Agreement without the invalid provision.

18.8 Force Majeure: Nonperformance of any party (except for payment obligations) shall

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be excused to the extent that performance is rendered impossible by strike, fire, earthquake, flood, governmental acts or orders or restrictions, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control and not caused by the negligence, intentional conduct or misconduct of the nonperforming party, provided such party uses its best efforts to resume performance as promptly as possible.

18.9 No Consequential Damages: In no event shall any party to this Agreement have any liability to the other for any special, consequential or incidental damages arising under this Agreement under any theory of liability.

18.10 Complete Agreement: This Agreement with its Schedules, constitutes the entire agreement between the parties with respect to the subject matter hereof, and all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be null and void and of no effect. No amendment or addition hereto shall be effective or binding on either of the parties unless reduced to writing and executed by the respective duly authorized representatives of Organogenesis and Sandoz.

18.11 Dispute Resolution: Any dispute under this Agreement which is not settled by mutual consent shall be finally settled by binding arbitration, conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association by three arbitrators appointed in accordance with said rules. The arbitration shall be held in New York, New York and at least one of the arbitrators shall be an independent expert in pharmaceutical product development (including clinical development and regulatory affairs). The costs of the arbitration, including administrative and arbitrators' fees, shall be shared equally by the parties. Each party shall bear its own costs and attorneys' and witness' fees. A disputed performance or suspended performances pending the resolution of the arbitration must be completed within thirty (30) days following the final decision of the arbitrators or such other reasonable period as the arbitrators determine in a written opinion. Any arbitration subject to this Section 18.11 shall be completed within one (1) year from the filing of notice of a request for such arbitration.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their authorized representatives and delivered in duplicate originals as of the Effective Date.

SANDOZ PHARMA LTD.

ORGANOGENESIS INC.

By: /s/ D. Vasella /s/ U. Oppikofer

By: /s/ David T. Rovee

Name: D. VASELLA U. OPPIKOFER

Name: David T. Rovee

Title: CEO Sandoz Exec. VP Sandoz

Title: President